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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 2-21

<u>TITLE</u>: Preparation and Revision of the IRIS Draft Toxicological Reviews of tert-Butanol (CASRN: 75-65-0) and ETBE (CASRN: 637-92-3)

Specify Section & Paragraph SOW: Please select from the following: Assessment Issues and Documents

- 1. Human Health Assessment Documents
- E. Risk Assessment Support
- F. Information Management

PERIOD OF PERFORMANCE: 11/1/2015 to 10/31/16

I. PURPOSE

This work assignment is a follow-on to work performed under Work Assignment # 0-21 and 1-21. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of revisions to the draft IRIS Toxicological Reviews of *tert*-butanol and ETBE. The overall objective of this WA is to provide administrative, logistical, and scientific support for draft development of the human health risk assessments for *tert*-butanol and ETBE.

This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

IRIS is an EPA data base containing Agency scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS currently provides health effects information on over 500 chemical substances.

IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

EPA will hold a bimonthly public meeting to provide an opportunity for input and discussion on preliminary materials for IRIS chemicals prior to the development of the assessments. The objective of this public meeting is to obtain input from stakeholders and the public on the studies and data that may be used to characterize hazard and exposure-response relationships and to develop toxicity values. Specifically, EPA is seeking input on preliminary materials including draft literature searches and associated search strategies, evidence tables, and exposure-response arrays for chemicals prior to the development of the IRIS assessments.

The overall goal of the human health risk assessments is to provide scientifically-defensible reasoning for the choice of critical cancer and non-cancer effects due to chemical exposure, along with the literature and principal study(ies) that best represent and support that choice. The Work Assignment Manager (WAM) will provide technical direction as necessary.

III. STATEMENT OF WORK

Task 1: Technical Editing of the Draft Toxicological Review of tert-butanol and ETBE, and IRIS Summaries

The Contractor shall conduct technical edits of the Toxicological Review prior to release for public comment/external peer review and prior to posting on the IRIS web site. The Contractor shall also conduct a technical edit of the IRIS Summary prior to posting.

Technical editing, which involves the reworking of written technical material for a specialized audience, may include: arranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; standardizing symbols; verifying and restyling reference citations where required; and cross-checking information in text, tables, and figures, as well as correcting errors in grammar, spelling, and punctuation. This work shall be performed according to EPA guidance related to the technical editing; the Handbook for Preparing NCEA Documents shall be used as a primary reference to resolve issues involving usage and style. All products will be formatted using current versions of IRIS Summary and Toxicological Review templates. The reference list shall be formatted according to the output in HERO (i.e., the HERO format supersedes the Handbook for Preparing EPA Documents). Technical editing includes:

- a. Mechanical editing Close reading of the manuscript to ensure correct grammar, spelling, syllabification, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; agreement of pronouns; correct use of adverbs and adjectives; beginning and ending quotation marks and parentheses; correct use of ellipsis; cross-checking contents with text to verify accuracy and consistency of headings, subheadings, and page numbers; and many other details of style.
- b. Substantive editing Involves any or all of the following: arranging or rearranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc; standardizing symbols; verifying and restyling reference citations; cross-checking information in the text to tables, figures, appendices, and references and correct apparent disagreements; correcting inconsistencies in format and style.
- c. Checking references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verifying accuracy, completeness, and adherence to established format. In the event that information is missing, consulting authors or procuring copies of cited material to complete reference.
- d. HERO links HERO links shall be added to any text in which links were not included.

The Contractor shall provide a final electronic mark-up (in 'Track Changes' format of Microsoft Word) of the draft Toxicological Review of Hexavalent Chromium and the IRIS Summary to the WAM no more than 20 days after receipt of the draft document from the WAM.

Task 2: Updates to Literature Search

The Contractor shall perform literature search updates during the review processes at regularly scheduled intervals during assessment development (i.e., through release for external peer review) and at least once after external peer review. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the Contractor. The literature search strategy shall be consistent with the strategy for the initial hexavalent chromium literature search conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The

Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further consultation.

Task 3: Maintenance of the HERO Database for tert-butanol and ETBE

The Contractor shall perform the following to ensure the HERO database is up to date with the most current Toxicological Reviews of tert-butanol and ETBE:

- Ensure that all literature referenced in the IRIS document can be found in HERO
- Ensure that references listed in HERO for a "tert-butanol" or "ETBE" search but are not referenced in the IRIS document do not contain tags that suggest otherwise
- Ensure that references are appropriately tagged, both in their HERO listings and in the hyperlinks embedded in the document
- Ensure that retrieved pdfs of references in the IRIS document are uploaded to HERO

OPTIONAL TASKS

The following tasks are optional. If EPA determines the services under these tasks are required, the EPA WAM will initiate by issuing written technical direction. These optional tasks should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 4: Update and Quality Assurance of Evidence Tables

The Contractor shall provide support to EPA in performing updates and quality assurance checks of tables that summarize organ-specific toxicity in human studies and animal bioassays (i.e., evidence tables). Updates of evidence tables shall be performed to add new studies identified through literature search updates performed during development of the draft assessment or during review steps. Quality assurance checks shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m³), confirming effect levels, and inserting and verifying HERO links. For each health effect category, separate evidence tables will be developed (if data are available), and all routes of exposure will be considered, including inhalation, oral, and dermal. The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. These tables will be provided to the Contractor by the WAM.

Optional Task 5: Additional Dose-Response Modeling

Additional endpoints may be identified by the WAM that need to be modeled. The Contractor shall use the most recent version/updates of EPA's BMDS. The Contractor shall:

- i. Model all endpoints as requested by the WAM, where the data set supports modeling.
- ii.Identify data that may not be amenable or reliable to model.
- iii.Identify important or unusual statistical uncertainties in the data or the fitted models.
- iv.Adhere to EPA's most recent BMD Technical Guidance¹ in conducting the modeling. If any exceptions to the guidance are used in an analysis (e.g., by disabling default parameter constraints) these exceptions should be noted and explained.

¹ U.S. EPA (2000) National Center for Environmental Assessment, Benchmark Dose Technical Guidance Document. Available from: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=22506

- v.Be cognizant of the information contained in BMDS help/training materials² when modeling the data or comparing models. Deviations may be allowed if adequately explained and justified to Agency experts.
- vi.For dichotomous data, derive three candidate points of departure (PODs) for each endpoint (i.e., BMDL10, BMDL5, BMDL1). For continuous data, derive PODs using a BMR of one standard deviation from the control mean.
- vii.For all models fitted, report, in a tabular format, key statistics for model goodness-of-fit (e.g., chi-square statistic and associated p-value) and model comparisons (e.g., Akaike's Information Criterion (AIC) value).
- viii.In conducting model comparisons and selecting models, EPA guidelines should be followed3. Deviations may be allowed if adequately explained and justified to Agency experts.
- ix. In selecting models, the following guidelines should be adhered to, but deviations may be allowed if adequately explained and justified to Agency experts.

Testing goodness-of-fit

- a. The chi-square goodness-of-fit p-value should be > 0.1.
- b. All chi-squared residuals < 2.0.
- c. By visual inspection, the model should exhibit a reasonable fit to the data.

Model selection

a. Models with the lowest AICs are preferred. Models with AICs that differ by less than 0.5 or so are generally considered not significantly different from one another.

Optional Task 6: Preparation of Exposure-Response Arrays

The Contractor shall develop exposure-response arrays, i.e., figures that provide a visual display of information in evidence tables. In general, a figure will be developed for each health effect category, with separate figures developed for oral and inhalation study information. The Contractor shall consult with EPA to determine the data sets to be represented in each array and the order of these data sets on the array. At present, EPA is typically using Microsoft Excel for generating these arrays. The Contractor may be asked to consider alternative software for generating these figures.

Optional Task 7: Support in Addressing Comments on the Toxicological Reviews following the Public Bimonthly Meeting and Various Review Steps

The Contractor shall provide support to the EPA in addressing comments received during the public bimonthly meeting and various review steps, including Agency review, interagency review, external peer review, and public comment. EPA cannot anticipate the number or nature of comments that will be received at each review step or the specific type of Contractor support that will be required following any given review step. EPA estimates that support will consist of the following tasks: summarize comments by topic or issue, research special topics or issues that may be raised in comments, conduct additional BMD or other modeling/analysis as appropriate, revise the Toxicological Review in response to comments, and assist in developing written responses to comments. The Contractor may also be asked to populate Comment-Tracker, an Access database developed by EPA to manage comments (and responses) on the draft assessment. The Contractor may also be asked to attend the interagency review meeting (via teleconference) and take notes during that meeting for internal use. All of these tasks will require a quick turn-around time.

³ U.S. EPA supra notes 1, 2, and 4

² U.S. EPA NCEA supra note 1.

Optional Task 8: Preparation of IRIS Summary

Prior to final Agency review and interagency science discussion, the Contractor shall prepare the IRIS Summary. The IRIS Summary shall be developed using the latest IRIS Summary template (to be provided by the WAM) and instructions for IRIS Summary development in the SOPs. The IRIS Summary shall be generated by extracting appropriate text from the current draft Toxicological Review (i.e., the draft that reflects revisions in response to external peer review comments). Little new writing will be required. The WAM will provide the Contractor with the appropriate draft of the Toxicological Review to use in developing the IRIS Summary. The Contractor shall submit the draft IRIS Summary to the WAM for review.

The WAM will provide to the Contractor EPA's comments on the draft IRIS Summary. The Contractor shall revise the IRIS Summary based on EPA's comment and submit the revised final draft IRIS Summary to the WAM.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1: Technical Editing of the Draft Toxicological	No more than 20 days after receipt of the draft Toxicological
Reviews and IRIS Summaries	Reviews and no more than 10 days after receipt of the IRIS
	Summaries from WAM
Task 2: Updates to Literature Search	For each update, no more than 30 days after initiation of
	literature search
Task 3: Maintenance of the HERO Databases	To be performed concurrent with literature search updates
Optional Task 4: Update and Quality Assurance	No more than 7 days after discussion with WAM
of Evidence Tables	
Optional Task 5: Additional Dose-Response	No more than 7 days after discussion with WAM
Modeling	
Optional Task 6: Preparation of Exposure-Response	No more than 7 days after discussion with WAM
Arrays	y .
Optional Task 7: Support in Addressing Comments	To be determined based on the nature of the Contractor support
on the Toxicological Reviews following Various	required
Review Steps	
Optional Task 8: Preparation of IRIS Summary	7 days after final draft Toxicological Review is provided to the
	Contractor by EPA
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Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Janice S. Lee

Telephone: 919-541-9458

Fax: 919-541-2985

e-mail: lee.janices@epa.gov

Mailing Address:

U.S. Environmental Protection Agency

Mail code B-243-01

RTP, NC 27711

Overnight Delivery location:

U.S. Environmental Protection Agency (B243-01)

4930 Page Road

Durham, NC 27703

Alternate Work Assignment Manager:

Keith Salazar

Telephone: 703-347-0278

Fax: 703-347-8689

e-mail: salazar.keith@epa.gov

Mailing Address:

USEPA Headquarters Ariel Rios Building 1200 Pennsylvania Avenue, N. W. *Mail Code:* 8601P Washington, DC 20460

Overnight Delivery location: Potomac Yards North 2733 Crystal Drive Rm # N7845 Arlington, VA 22202

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.)	Bibliographic identification of the study.
	Study Identifiers: Author(s): Title: Study Citation: Storage location (e.g., library, facility archive, personal archive):
2.)	Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
3.)	Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
4.)	Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
5.)	Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
6.)	Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:
	Are research questions clearly stated; dependent and independent variables clearly defined?
	Do the authors explain the type of data obtained from measures of the variables?
	Are statistical methods adequately described; are they justified?
	Is a source provided for the any statistical software used to analyze the data?
	Is the purpose of the analysis clear?
	Are any scoring systems described?
	Are potential confounders adequately controlled for in the analysis?
	Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?
	Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 2-24

TITLE: Exposure assessment of livestock carcass management options

Specify Section & Paragraph SOW: A2 Exposure Assessment Documents.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Hazards associated with livestock carcass management options following a natural disaster, foreign animal disease outbreak, and chemical/radiological attacks
- Exposure pathways associated with each identified carcass management option
- Calculated exposures for each exposure pathway with sufficient data to quantify
- Levels of uncertainty in the calculated exposures
- Carcass management options that are the least likely to result in exposure impacts to additional livestock, human health, and/or the environment
- Knowledge gaps for further study to help minimize uncertainties in the assessment

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents.

Under the National Response Framework, EPA is a support agency for federalized responses to Foreign Animal Disease (FAD) outbreaks, providing support to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS). One of the likely areas where EPA might provide support to USDA/APHIS is in helping to assure the proper management of animal carcasses following major event such as a natural disaster or FAD outbreak. Currently, there are several accepted carcass management options including rendering, composting, sanitary landfills, permitted incinerators, open burning, and unlined burial (Figure 1). Given the incident-specific nature of a massive carcass management response, there are knowledge gaps in comparing these management technologies from environmental, cost, human health, and animal health standpoints. Developing a risk-based methodology to allow decision makers to select the most appropriate carcass management technology for a given incident would significantly improve the Nation's preparedness.

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Carcass Management Options Processes										
Rendering				transport to rendering		grind carcasses	cook	manage steam, tallow, and meal		
Sanitary Landfill	¥		¥	transport to landfill		bury carcasses	manage leachate, landfill gas, and solids		Human, Ecological, and Livestock Health Risks	
Permitted Incinerator	Load animal into truck	Cover truck	decon outside of truck	transport to incinerator	unload truck	load animals into incinerator	process	manage air emissions and ash	and Livestoc	
Composting	Load an	Load an	decon c	transport to compost area	lun	build windrows		e finished npost	, Ecological,	
Open Burning				transport to burn site		burn carcasses		leachate, d smoke	Human	
Unlined Burial				transport to burial site		bury carcasses	7.000	manage methane and leachate		

Figure 1. Potential carcass management option processes to evaluate for associated hazards and exposure pathways.

III. TASKS

Task 1: Workplan

The contractor shall generate a workplan describing how tasks 2-5 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations. The workplan shall outline the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships. The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WAO-24).

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Deliverables: Workplan and Project Management file

Task 2: Carcass Management Options Processes Conceptual Models and Analysis Plans

The contractor shall develop conceptual models for each of the identified carcass management options for each phase of the project. The conceptual models will qualitatively describe the management options processes to describe suspected sources, potential pathways of exposure, and potential receptors. The models shall concisely convey the underlying assumptions of the exposure assessment and how the exposure of receptors will be modeled to occur. The carcass management options conceptual models shall be developed based on available information regarding the potential fate, transport, and exposure route. The contractor shall develop preliminary analysis plans to accompany the conceptual models to identify the types of data and models that are likely be needed and any known sources of relevant information. In addition, the preliminary analysis plans will propose quantitative methods (e.g., environmental modeling), exposure metrics (based on the problem formulation), and the data needed to facilitate ranking management options by relative exposure potential. The plan also will discuss uncertainties associated with data gaps and modeling and methods for characterizing uncertainty when ranking exposures.

Deliverable: Conceptual Models Document and Analysis Plans

Performance Standard: The contractor shall provide the draft conceptual models with accompanying analysis plans document within 2 months after approval of the work plan.

Task 3: Data Gathering and Literature Review

The contractor shall conduct a thorough literature review to assess the availability of data to quantify the potential exposure doses for each identified exposure pathway in the carcass management process conceptual models for each phase of the project.

Deliverables: Literature Reviews

Performance Standard: The contractor shall provide the draft literature review and expert workshop report within 4 months after approval of the conceptual models document.

Task 4: Quantification of Potential Exposure Pathways and Relative Ranking of Management Options Final Report

The contractor shall compose a final report for the exposure assessment to include results of the previous tasks (final problem formulation, refined conceptual models, and gathered expert input and literature data). In the final report, the contractor shall also refine the conceptual models exposure pathways based on the available data from the literature and expert input to quantify potential exposures. For each identified management option, the potential exposures shall be quantified for each exposure pathways for each identified hazard. The contractor shall develop a relative ranking of the carcass management options and identify all assumptions, variabilities, and uncertainties. The final report shall also identify knowledge gaps where further study could help to minimize the uncertainty associated with the results of the exposure assessment.

Deliverables: Final Report

Performance Standard: The contractor shall provide the draft final report within 6 months after approval of the literature review.

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Task 5: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WA-COR and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WA-COR on request within two weeks of the request. The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WA-COR. All documents or presentations associated with this project shall be cleared through WA-COR prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WA-COR prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WA-COR. WA-COR shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WA-COR with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WA-COR shall be provided to WA-COR either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WA-COR. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by WA-COR, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Work Plan	Contractor shall provide the completed Work Plan within 30 days of award	WA-COR shall document whether receipt of Work Plan is timely and acceptable, and provide technical revisions as required
	Revised Work Plan	Contractor shall revise Work Plan if required and submit final Work Plan no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised Work Plan, and ensure that is timely and technically acceptable
2	Conceptual Models and Analysis Plans	Contractor shall provide the completed conceptual models and accompanying analysis plans within 2 months after approval of the Work Plan	WA-COR shall document the receipt of conceptual models and analysis plans, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
	Revised Conceptual Models and Analysis Plans	Contractor shall revise conceptual models and analysis plans if required and submit final models no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised conceptual models and analysis plans, and ensure that they are timely and technically acceptable
3	Literature Reviews	Contractor shall provide the completed literature reviews within 4 months after approval of the conceptual models	WA-COR shall document the receipt of literature reviews, and ensure that they are timely and technically acceptable, and provide technical comments as appropriate
	Revised Literature Reviews	Contractor shall revise literature reviews if required and submit reviews no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised literature reviews, and ensure that they are timely and technically acceptable
4	Final Report	Contractor shall provide the draft Final Report within 6 months after approval of the literature reviews and expert workshop report	WA-COR shall document the receipt of final report, and ensure it is timely and technically acceptable, and provide technical comments as appropriate
	Revised Final Report	Contractor shall revise final report if required and submit no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised report, and ensure it is timely and technically acceptable
5	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WA-COR briefly updating project progress	WA-COR shall participate in these calls to identify any issues to be addressed in the research or future reports
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WA-COR shall document receipt of monthly reports and ensure that these are timely and acceptable

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Meetings with WA-COR Contractor with the W	shall have periodic meetings A-COR as needed	WA-COR shall participate in these meetings and identify any issues to be addressed
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VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- 1. Formulation of Agency policy
- 2. Selection of Agency priorities
- 3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR

WA-COR:

Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7037
Cell 513/288-5460
Taft.Sarah@epa.gov

Alternate WA-COR:

Paul Lemieux, Ph.D.

U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT National Homeland Security Research Center 109 TW Alexander Drive (E343-06) Research Triangle Park, NC 27711 Work 919/541-0962 Cell 513/300-9958 Lemieux.Paul@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

- (1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
- (2) an organizational chart showing the position of the QA function;
- (3) delineation of the authority and responsibilities of the QA function;
- (4) the background and experience of the QA personnel who will be assigned to the project; and
- (5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

Category I Project - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.
Category II Project - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

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	applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).
	Category IV Project - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below). Project Types:
to serve	These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where ise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must a populate to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the property of adequate quality and quantity to fit their intended purpose.
	Applied Research Project - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.
	Basic Research Project - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.
	Design, Construction, and/or Operation of Environmental Technology Project - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf . For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.
	Geospatial Data Quality Assurance Project - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf .
	Method Development Project - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.
	Model Development Project - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."
	Sampling and Analysis Project - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.
	Secondary Data Project - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.
	Software Development and Data Management Project - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

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Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

Contracting Officer's Representative COR

NHSRC National Homeland Security Research Center NRMRL National Risk Management Research Laboratory

QA ID Quality Assurance Identification QAPP Quality Assurance Project Plan

Quality System QS TLP Technical Lead Person Interagency Agreement IAG Quality Assurance QA

QAM Quality Assurance Manager Quality Management Plan QMP Statement of Work SOW

CRADA Cooperative Research & Development Agreement

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			Phone Number: 513-487-2852								

PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 2-26

TITLE: Board of Scientific Counselors (BOSC) Meeting / Conference Support

Specify Section & Paragraph SOW:

PERIOD OF PERFORMANCE: November 1, 2015 thru October 31, 2016

1. BACKGROUND

The primary functions of the BOSC include evaluating ORD's science and engineering research programs, laboratories, and research-management practices, and recommending actions to improve their quality and/or strengthen their relevance to the mission of the EPA. For more information on the BOSC, go to http://epa.gov/osp/bosc/.

2. PURPOSE

The purpose of this Work Assignment is to provide: a full range of administrative and logistical support services for the conduct of Federal Advisory Committee meetings, conferences and/or teleconferences related to the Charter of the Office of Research and Development's Board of Scientific Counselors (BOSC); administrative activities required for reports prepared by the BOSC Executive Committee or it's Subcommittees; and the full range of administrative support services for assimilating materials collected from extensive candidate searches conducted for either the Executive Committee, or existing or proposed Subcommittees.

The contractor's activities will not require special expertise in matters of science discussed by the Board, but the contractor should possess the practical knowledge, experience, and skills commonly used in facilitating high-level policy meetings.

Meetings of the BOSC Executive Committee and Subcommittees will generally be held on-site at US EPA (either Headquarters or a Laboratory/Center, as appropriate), if space is available, with the approval of the Designated Federal Officer (DFO). Under this work assignment, it is anticipated that contractor support shall be required for approximately four Executive Committee meetings (at least 1 is expected to be face-to-face meetings); approximately 5 face-to-face program review subcommittee meetings. In addition, contractor support shall be needed for approximately 17 conference calls (expected to be 2-3 hour calls) in support of the executive committee and subcommittee meetings. The EPA WAM will provide the meeting dates via written technical direction.

It is anticipated that approximately 6 reports shall be generated by the BOSC during the timeframe of this work assignment, and that candidate searches requiring contractor support may occur no more than 2 times per year.

3. STATEMENT OF WORK

This Statement of Work describes EPA's requirements regarding services to be rendered by the contractor for BOSC meeting and conference support. The contractor shall provide the necessary personnel and resources in the following four areas for the BOSC:

- 1. Pre-meeting communication and logistical support.
- 2. On-site technical support during meetings/teleconferences.
- 3. Prepare summary minutes of meetings/teleconferences.
- 4. Word processing for reports.

Task 1. Pre-meeting communication and logistical support

As requested by the EPA WAM, the contractor shall prepare a BOSC member's background binder for the list of invitees provided by the EPA WAM, to include agenda, minutes of last meeting (if appropriate), other background/logistical material needed for the meeting/teleconference. Via written technical direction, the meeting/teleconference dates will be provided by the EPA WAM. The contractor shall prepare a mail merge file and address labels for the list of members and invitees. All correspondence shall be transmitted under the Designated Federal Officer's name. It is anticipated that there will be approximately 30 participants for each Executive Committee meeting, and approximately 20-100 participants for each Subcommittee face-to-face meeting.

The contractor shall obtain meeting space facilities when government owned facilities are not available, as determined by the EPA WAM (this includes negotiation with hotels or other entities to obtain meeting space, as well as reservations (room blocks) for lodging that fall within U.S. Government per-diem rates and meet Agency lodging requirements).

Task 2. On-site technical support during meetings/teleconferences

The contractor shall provide recorders to take minutes at each meeting/teleconference. The contractor shall ensure that all equipment needed at the meeting is available, to include microphone equipment, laptop computers, etc., as needed and specified by the EPA WAM.

The contractor shall provide a registration table each day of the meeting and shall provide table tents and name badges of participants. The contractor shall also photocopy additional sets of handouts and materials as may be required during the course of the meeting, on a fast turnaround basis, as requested by the EPA WAM.

The contractor shall deliver to the EPA WAM any materials not distributed at the meeting or materials left behind by BOSC members within two working days after the meeting.

Task 3. Prepare summary minutes of meetings/teleconferences

The contractor shall prepare and submit to the EPA WAM draft minutes of the meetings/teleconferences within 15 working days of the end of each meeting/teleconference. The contractor shall incorporate comments and changes to the minutes per written technical direction by the EPA WAM and submit final minutes within 5 working days of receiving EPA comments. The draft and final minutes shall be provided in electronic format (Word is the Agency standard software).

Task 4. Word Processing for Reports

The contractor shall provide word processing support for any reports prepared by the BOSC Executive Committee or its Subcommittees. The contractor shall not be involved in developing the technical content of the report, and shall not provide any scientific technical expertise. The contractor shall only provide word processing services to compile, format, edit (based on Executive Committee and Subcommittee member input, plus any factual changes requested by ORD and approved by the Executive Committee), and finalize reports prepared by the Executive Committee or its Subcommittees.

The contractor shall compile/format/edit and submit draft Executive Committee/ Subcommittee reports to the EPA WAM within 15 working days after receiving report content. The contractor shall incorporate comments and changes to the reports and submit final reports to the EPA WAM within 5 working days of receiving comments. The draft and final reports shall be provided in electronic format (Word is the Agency standard software).

5. SCHEDULE OF DELIVERABLES

Product	Due Date
Logistical Arrangements of Meeting	30 working days prior to meeting
Draft Minutes of Meeting (To EPA WAM)	15 working days after completion of meeting
Final Minutes of Meeting (to EPA WAM)	5 working days after receipt of comments from EPA WAM
Draft Exec Committee/Sub- committee reports (to	15 working days after receipt of report EPA WAM) content from EPA WAM
Final Exec Committee/Sub-committee reports (to	5 working days after receipt of comments EPA WAM) from EPA WAM

6. SPECIAL CONDITIONS

Final products shall be produced by the Contractor upon EPA WAM's approval through written technical direction. The Contractor shall provide all materials written under these tasks to the EPA WAM, as per work assignment, in electronic form. Electronic version shall be compatible with the ORD's computer systems and software, (e.g., Microsoft Word).

Separate from the Monthly Progress Report, the contractor costs shall be provided to the EPA WAM on a monthly basis, and shall be compiled separately for the Executive Committee and each Subcommittee. EPA is required to annually input cost information for each committee or subcommittee into a government-wide

database, and EPA will not be able to comply with this federal requirement unless contractor costs are tracked and reported to EPA by each committee/subcommittee.

7. CONFIDENTIALITY

Some of the work assigned under these tasks may be to draft, edit, and review program and sensitive organizational information that will not be ready for broad or public distribution. The contractor shall not discuss the contents of any document with anyone not specified as a participant in the documents review process or its preparation. The EPA WAM will supply the contractor with a list of individuals involved with any documents under these tasks.

8. MANAGEMENT CONTROLS

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the PO and the WAM or alternate WAM are the primary representatives of the CO authorized to provide technical direction.

WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR

WA-COR:

Thomas Tracy
Designated Federal Officer
Board of Scientific Counselors
Office of Research and Development
U.S. Environmental Protection Agency
Mail Code 8104R
1200 Pennsylvania Avenue, NW
Washington, DC 20460

202-564-6518

Alternate WA-COR:

EPA		United	United States Environmental Protection Agency Washington, DC 20460					Work Assignment Number 2-26				
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 2-27

TITLE: Chemical Safety for Sustainability (CSS) meetings support

Specify Section & Paragraph SOW: E. Risk Assessment Support

PERIOD OF PERFORMANCE: 11/10/15 to 10/31/16

I. PURPOSE:

This work assignment is a follow-on to work performed in the Option Period 1 under Work Assignment #1-27. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) Immediate Office of the Assistant Administrator (IOAA), Office of Research and Development (ORD), in the completion of providing administrative and logistical/facilitation support services for one additional face-to-face meeting for the Chemical Safety for Sustainability (CSS) research program. This meeting will be held in Research Triangle Park (RTP), NC. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001, Section E. Risk Assessment Support of the HHRA PWS.

II. BACKGROUND:

Chemicals are a lynchpin of innovation in the American economy, and moving toward sustainable innovation requires designing, producing, and using chemicals in safer ways. Information and methods are needed to make better-informed, more-timely decisions about chemicals, many of which have not been thoroughly evaluated for potential risks to human health and the environment. EPA's chemical safety research is designed to meet this challenge and supports the Agency priority of reducing risks associated with exposure to chemicals in commerce, the environment, products and food.

The CSS Strategic Research Action Plan 2012-2016 (StRAP) provides the overall framework for CSS research. Fiscal year 2015 (FY15) planning presented an opportunity to conduct a mid-StRAP review of the program and look for ways to integrate the research, enhance transdisciplinary collaboration, promote and foster innovation, enhance transparency and access to CSS products, and significantly amplify the impact of this important research. The addendum to the CSS 2012-2016 StRAP was developed to facilitate integration of the CSS research program. Concurrently, ORD has been gathering input from stakeholders and partners in identifying the strategic directions necessary to develop an update to the StRAP for 2016-2019. The CSS research program is looking for logistical support for this meeting related to engaging our partners in order to finalize plans detailed in the 2016-2019 StRAP as well as to conduct efforts to describe and translate existing or soon to be released research project deliverables with our partners across EPA.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for one additional meeting in support of the CSS research program. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a may include a summary report (including meeting and breakout discussion notes), and communication activities related to the meeting. The CSS computational chemistry data pipeline stakeholder workshop meeting is planned for January or February 2016 and will be planned to take place in RTP. We anticipate this workshop to have 50-75 participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has or will reserve its own meeting room space for this meeting. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions necessary to draft a workplan that will outline tasks, deliverables and due dates. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for the meeting may include:
 - Develop a registration mechanism and coordinating registration, including maintaining a list of participants.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Preparation and distribution of meeting materials including final agenda, meeting roster, name badges and other meeting materials.
 - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
 - Setting up webinar, conference call and if applicable video conference capability for remote participation.

3. Onsite Logistical Support and Reporting

- Providing staff to support the meeting onsite.
- Capturing notes during the discussion including the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
- Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Manage speaker presentations to ensure presentations are loaded to the laptop, being projected and available following the event.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins).

• Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.

4. Follow-up Meeting Support

- Summarize in a report all meeting discussions including key decisions and actions items in a post-meeting summary report. This report should include a listing of all meeting attendees.
- Post materials to event webpage.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Initial contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	30 days prior to the meeting
Submit electronic copies of registration lists and registration materials;	Two working days before the meeting
Submit updated list of registered attendees (including walk-ins), electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following the meeting
Post-meeting final report(s)	Ten working days following the meeting

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any

of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Michael Loughran 202-564-6686 Loughran.Michael@epa.gov

Alternate WAM Joy Murphy 202-564-6651 Murphy.Joy@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 2-27

TITLE: Chemical Safety for Sustainability (CSS) meetings support

Specify Section & Paragraph SOW: E. Risk Assessment Support

PERIOD OF PERFORMANCE: 11/1/15 to 10/31/16

I. PURPOSE:

This work assignment is a follow-on to work performed in the Option Period 1 under Work Assignment #1-27. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) Immediate Office of the Assistant Administrator (IOAA), Office of Research and Development (ORD), in the completion of providing administrative and logistical/facilitation support services for one additional face-to-face meeting for the Chemical Safety for Sustainability (CSS) research program. This meeting will be held in Research Triangle Park (RTP), NC. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001, Section E. Risk Assessment Support of the HHRA PWS.

II. BACKGROUND:

Chemicals are a lynchpin of innovation in the American economy, and moving toward sustainable innovation requires designing, producing, and using chemicals in safer ways. Information and methods are needed to make better-informed, more-timely decisions about chemicals, many of which have not been thoroughly evaluated for potential risks to human health and the environment. EPA's chemical safety research is designed to meet this challenge and supports the Agency priority of reducing risks associated with exposure to chemicals in commerce, the environment, products and food.

The CSS Strategic Research Action Plan 2012-2016 (StRAP) provides the overall framework for CSS research. Fiscal year 2015 (FY15) planning presented an opportunity to conduct a mid-StRAP review of the program and look for ways to integrate the research, enhance transdisciplinary collaboration, promote and foster innovation, enhance transparency and access to CSS products, and significantly amplify the impact of this important research. The addendum to the CSS 2012-2016 StRAP was developed to facilitate integration of the CSS research program. Concurrently, ORD has been gathering input from stakeholders and partners in identifying the strategic directions necessary to develop an update to the StRAP for 2016-2019. The CSS research program is looking for logistical support for this meeting related to engaging our partners in order to finalize plans detailed in the 2016-2019 StRAP as well as to conduct efforts to describe and translate existing or soon to be released research project deliverables with our partners across EPA.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for one additional meeting in support of the CSS research program. Support will include planning for meeting and logistics, travel support, onsite meeting support and facilitation, a may include a summary report (including meeting and breakout discussion notes), and communication activities related to the meeting. The CSS Adverse Exposure Pathway (AEP) research workshop meeting is planned for May 9-11, 2016 and will be planned to take place in RTP. We anticipate this workshop to have 30-40 participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has or will reserve its own meeting room space for this meeting. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions necessary to draft a workplan that will outline tasks, deliverables and due dates. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for the meeting may include:
 - Provide support to invited participants (non-federal) for travel expense reimbursement.
 - o The Contractor shall arrange and provide for transportation, lodging, and logistical support for up to twenty experts asked to participate in the workshop.
 - Establish and monitor a registration website for each workshop and compile and maintain the
 workshop registration list. Provide updated registration lists to EPA on a weekly basis after
 registration opens and more frequently when registration deadlines are approaching.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Manage the collection of the experts' presentations and prepare electronic files needed during the workshop. Load all expert and EPA presentations on the computer to be used during the workshop.
 - Preparation and distribution of meeting materials including final agenda, meeting roster, name badges and other meeting materials.
 - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
 - Setting up webinar, conference call and if applicable video conference capability for remote participation.

3. Onsite Logistical Support and Reporting

- Providing staff to support the meeting onsite for 2 days, May 9-10.
- Capturing notes during the discussion including the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
- Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Manage speaker presentations to ensure presentations are loaded to the laptop, being projected and available following the event.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
- Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.

4. Follow-up Meeting Support

- Summarize in a report all meeting discussions including key decisions and actions items in a post-meeting summary report. This report should include a listing of all meeting attendees.
- Post materials to event webpage.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Initial contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	45 days prior to the meeting
Submit electronic copies of registration lists and registration materials;	Two working days before the meeting
Submit updated list of registered attendees (including walk-ins), electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following the meeting
Post-meeting final report(s)	Ten working days following the meeting

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Michael Loughran 202-564-6686 Loughran.Michael@epa.gov

Alternate WAM
Joy Murphy
202-564-6651
Murphy.Joy@epa.gov

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